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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,737	10/08/1999	DIETER NEUSER	BAYER10197	6345

7590

04/09/2003

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EXAMINER

GEORGE, KONATA M

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/402,737

Applicant(s)

NEUSER ET AL.

Examiner

Konata M. George

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10,11 and 14 is/are allowed.
- 6) ☒ Claim(s) 1-9,12,13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received..
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-15 are pending in this application.

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 27, 2003 has been entered.

Action Summary

2. Examiner acknowledges the addition of claims 13-15.
3. The rejection of claims 1-9 and 12 under 35 U.S.C. 103(a) over Nelson is being maintained for the reasons stated in the office action dated August 27, 2002.

Response to Arguments

4. Applicant's arguments filed December 20, 2002 have been fully considered but they are not persuasive.

Applicants argue that dextromethorphan is "essentially free of analgesic properties" and that it would not be used in the treatment of pain and one of ordinary skill in the art would not use it to treat pain. Column 1, lines 37-41 teaches that it once was a longstanding belief that dextromethorphan had no significant analgesic activity, *however* (word and emphasis added) "it has now been discovered that dextromethorphan is useful in the treatment of mouth pain". So it is the position of the

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examiner that although in the past that dextromethorphan was not used to treat pain it was recently discovered that it could be. Therefore, it is the position of the examiner that Nelson reads on the claimed invention. Further, applicants argue that the limitations of claims 6-9 are not taught. Page 3 of the specification teaches that the limitations of these claims are conventional formulations produced by conventional methods. Nelson, in column 2, lines 52-56 teach conventional formulations such as lozenges, coated pastilles and hard carmel would have been obvious. Applicants do not produce any teachings that patentably is dependent on these conventional formulations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9, 12, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson (US 4,446,140).

Nelson discloses a method and composition for treating mouth pain. The prior art teaches that it has discovered that dextromethorphan is useful in the treatment of mouth pain and the temporary reduction of such pain (col. 1, lines 37-41). It is the opinion of the examiner that dextromethorphan used in this invention is acting or has the properties of an analgesic. The invention further contains in addition to the dextromethorphan a conventional analgesic or anesthetic such as ibuprofen, naproxen

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or butacaine (col. 1, lines 49-57 and col. 2, lines 18-32). The pharmaceutical composition may be in a form suitable for oral use (col. 2, lines 52-56). The prior art does not teach the time of the duration of action.

It is the position of the examiner that the time of the duration of action would have been obvious to one of ordinary skill in the art. The composition of Nelson is being used to treat month pain by administering dextromethorphan and an additional analgesic or anesthetic, and since it would be obvious to treat month pain as quick as possible one would administer a drug that has rapid action. It would also be obvious to sustain the pain relieving action over a long period of time by employing a drug that has that characteristic.

Allowable Subject Matter

6. Claims 10, 11 and 14 are allowed.

Telephone Inquiries

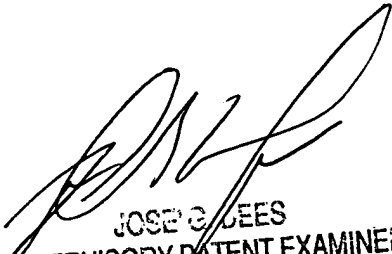
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George


JOSE G. LEES
SUPERVISORY PATENT EXAMINER
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